

PATIENT INFORMATION
BROCHURE



AFFINITY™ CAGE SYSTEM

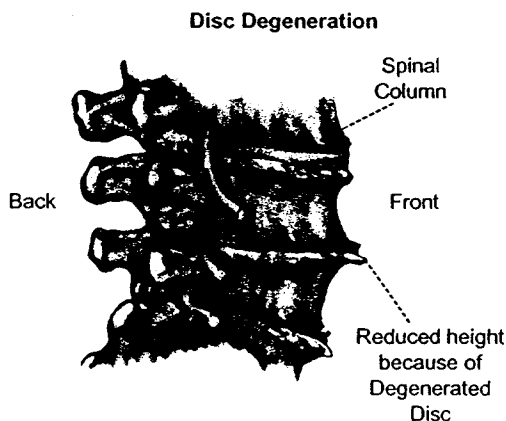
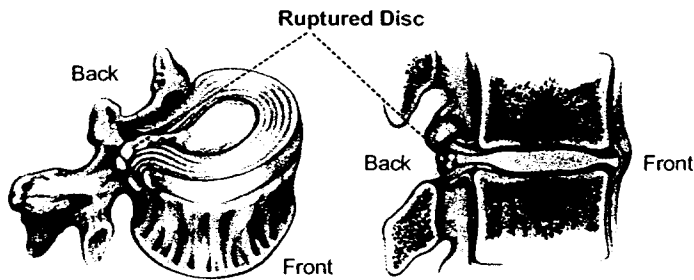
This Patient Guide is designed to help you make an informed decision about treatment for your neck pain and related problems. Your doctor has proposed surgery to relieve your neck discomfort using the AFFINITY™ Cage System. The purpose of this brochure is to give you some background about neck surgery and this medical device system.

DISC PROBLEMS

Some common causes of neck problems are disc injury that can result in a protrusion or bulge at the disc called a herniation or rupture, and disc degeneration which is the deterioration of the disc over time. Disc degeneration affects about 12 million people in the U.S., of which most are within the ages of 20 to 65.

Pressure on the Nerve

The AFFINITY™ Cage System was designed to aid in the treatment of disc disorders.



Persistent pain in your neck can be frustrating because it limits your ability to move and do the things you enjoy. To manage your neck pain problem, you may have followed your doctor's non-operative treatment plan—rest, medication, physical therapy, and exercise. But, despite your best efforts, the pain won't go away.

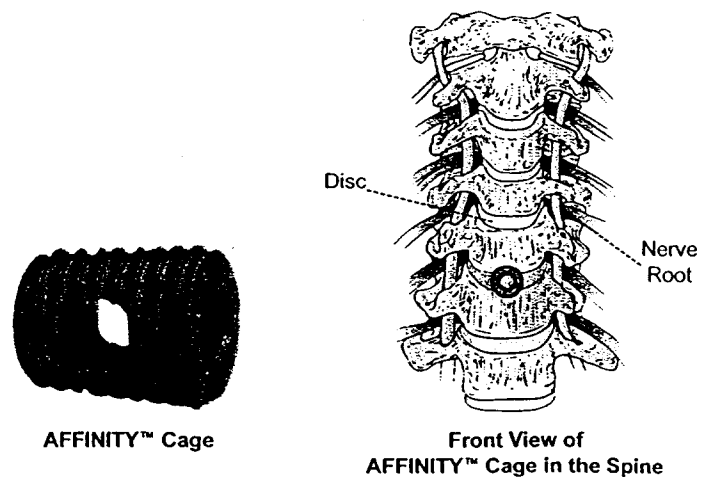
YOUR NECK

The bony vertebrae, which encircle and protect your spinal cord, are separated by shock-absorbing discs. The discs give your spine the flexibility to move. Nerves branching from the spinal cord pass through openings in the vertebrae to other parts of your body. As discs lose their water content because of disease or age, they lose their height, bringing the vertebrae closer together. The consequence is a weakening of the shock absorption properties of the disc and a narrowing of the nerve openings in the side of the spine that pinch your nerves. Disc degeneration may cause neck pain and may cause numbness in the upper extremities as well. Each disc has a spongy center (nucleus) surrounded by tough outer rings. Wear and tear, poor posture and incorrect body movements can weaken the disc.

SURGICAL INTERVENTION

The AFFINITY™ Cage System is a small, metal, hollow, threaded tapered device that is intended to stabilize or fuse the spine thereby relieving the pressure on your nerves. Typically, one or two implants are used. The AFFINITY™ Cage System may only be used at one disc level.

During your surgery, your doctor will remove portions of the degenerated disc and vertebral body to allow the implants to be inserted. Bone will then be taken from your hip and packed inside the hollow implants.



WHEN SHOULD THE AFFINITY™ CAGE SYSTEM NOT BE USED?

The AFFINITY™ Cage System should not be used if you have an active infection or if you have an allergy to titanium or titanium alloy.

RISKS

Although this treatment may help relieve your pain, any cervical surgery is not without risks. A variety of complications, some of which may be severe, may occur affecting your outcome.

complications reported from the clinical trial of the AFFINITY™ Cage System are as follows:

- new or continued neck and/or arm pain
- spinal events including narrowing of the spinal canal, bone spurs, ligaments in the neck turning to bone, bulging or defects in the discs, disruption that allows leakage from the center of the disc
- gastrointestinal events
- neurological events such as pain that occurs in the upper or lower body
- other pain such as bursitis, knee pain, etc.
- failure of the device to fuse the neck
- painful speaking or swallowing
- carpal tunnel syndrome
- infection
- cardiovascular events
- graft site related pain and/or infection
- urogenital events
- cancer
- sinking of implant into bone
- difficulty in placement of device during surgery
- dural tear
- malpositioned implant
- trauma including falls, motor vehicle accidents, bicycle accidents, etc.
- other events that may not be related to the treatment such as psychological disorder, allergies, toothache, etc.

Specific information on the rates and types of complications, and whether the complications are related to the AFFINITY™ Cage System treatment can be discussed with your doctor.

In addition to those listed above, other complications may occur that contribute to your surgery being unsuccessful. An additional surgery may be needed to resolve the complication. The additional surgery

may include removal of the device, adjusting or modifying the device, or adding additional spinal devices that are not part of the original device. See table below.

Table I - Secondary Surgical Procedures										
Type of Secondary Surgical Procedure	Postop (1 Day to 2 Months)		3 Months (2 Months to 5 Months)		6 Months (5 Months to 9 Months)		12 Months (9 Months to 19 Months)		24 Months (or greater) (19 Months to 48 Months)	
	Affinity™ N=202	Control N=62	Affinity™ N=191	Control N=58	Affinity™ N=186	Control N=57	Affinity™ N=178	Control N=50	Affinity™ N=174	Control N=47
Additional Surgical Procedures: Related to Device	1%	2%	0	2%	3%	4%	2%	6%	3%	4%
"Other" Surgical Procedures?	0	0	2%	0	4%	2%	8%	8%	2%	6%

¹ Control patients received only bone to fuse the neck.

² Other surgical procedures are second surgeries that did not occur at the treatment level such as surgeries for hernias, rotator cuff tears, lumbar adverse events, carpal tunnel syndrome, or cervical adverse events that occurred at a different level.

BENEFITS

The use of the AFFINITY™ Cage System in a cervical surgery may be successful in relieving your neck discomfort associated with disc degeneration or herniation. In the clinical trial, overall success was the primary endpoint of the AFFINITY™ Cage System based on predefined outcome measurements. A patient was an overall success if all of the following conditions were met: the treated level fused; there was relief from neck pain and disability based on a questionnaire completed by the patient; neurological evaluations done by the surgeon were maintained or improved; and the patient did not have a second surgery due to an unsuccessful initial surgery. At twenty-four months following surgery, 68% of the patients receiving the AFFINITY™ Cage System were an overall success, as compared to 61% of the control treatment group.

AFTER SURGERY

Ask your doctor about your specific recovery plan following surgery. It is important to follow your doctor's instructions carefully to recover from surgery as quickly as possible and increase your chances of a successful outcome.

Recovering from neck pain and surgery is an ongoing process. How fast you recover depends on the type of surgery you had, your commitment to working closely with your physical therapist, and moving and exercising correctly, as recommended by your surgeon.

Physical Therapy

After surgery, your surgeon may refer you to a physical therapist who will teach you exercises to improve your strength and increase your mobility. The goal of physical therapy is to help you become as soon as possible, using safe body movements that protect your back and neck.

YOUR ROLE IN RECOVERY

It's up to you to follow your surgeon's recommendations, such as seeing your physical therapist regularly. Remember to move and exercise properly as you return to a more active lifestyle.

Good body mechanics keep your neck well-aligned and reduce pain, but maintaining a safe, balanced position may require some changes in how you go about daily activities. For instance, you may need to learn different ways of standing, sitting, or lifting to avoid reinjuring your neck.

Exercise Regularly

Your recovery plan prescribed by your doctor may include back and neck exercises to strengthen muscles that help support your neck. Done regularly, or your doctor's supervision, these exercises can help you build the strong, flexible muscles you need to protect your neck.

Follow-up Care

You and your surgeon will continue to work together during your recovery. Before you leave the hospital, your surgeon may schedule follow-up visits with you so that he or she can evaluate your progress, advise you about your activity level, and adjust any medication, if necessary. Sometimes your doctor may recommend follow-up tests to make sure you are healing properly.

POSSIBLE OUTCOMES AND COMPLICATIONS

Consult your physician for expected treatment results for your situation. He or she will have the results from the clinical study that evaluated the device and be in a position to relate the results to your particular case.

Information You Should Be Sure to Tell Your Surgeon

1. That you may be pregnant
2. That you need to take steroidal or non-steroidal anti-inflammatory medications
3. That you think you may have an infection
4. That you are allergic to a drug

Questions You May Wish to Ask Your Doctor

1. Will there be much pain after the surgery?
2. How long will I have to stay in the hospital?
3. How long do you think I will have to stay home from work?
4. What restrictions will I have while I am recuperating?
5. Will my body have a reaction to the implant?
6. Will the implant stay in my body the rest of my life?
7. Will insurance be likely to pay for this surgery?
8. Will I eventually be able to return to my normal level of activity?

COMMENTS

This patient guide is made possible through cooperation between your physician and Medtronic Sofamor Danek.

While this brochure has hopefully provided you with the information you need to make an informed decision about your treatment options, it is not intended to replace professional medical care or provide medical advice.

If you have any questions or need additional information about the AFFINITY™ Cage System, please call or see your doctor, who is the only one qualified to diagnose and treat your neck.